

the product's impact on the environment.

[26 FR 7726, Aug. 18, 1961, as amended at 30 FR 11848, Sept. 16, 1965; 52 FR 30131, Aug. 13, 1987; 56 FR 66783, Dec. 26, 1991; 75 FR 20772, Apr. 21, 2010]

## PART 104—PERMITS FOR BIOLOGICAL PRODUCTS

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AUTHORITY: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 38 FR 32916, Nov. 29, 1973, unless otherwise noted.

### § 104.1 Permit required.

Unless otherwise authorized or directed by the Administrator, each permit to import a biological product into the United States shall be issued in accordance with the regulations in this part.

(a) No biological product shall be brought into the United States unless a permit has been issued for such product. A separate U.S. Veterinary Biological Product Permit shall be required for each shipment of biological product to be imported: *Provided*, That, a permit shall also be required for each transit shipment of biological products moved through the United States.

(b) Each person importing biological products shall hold an unexpired, unsuspended, and unrevoked permit issued by Animal and Plant Health Inspection Service. Such person shall reside within the United States, or operate a business establishment within the United States, or both.

[38 FR 32916, Nov. 29, 1973, as amended at 56 FR 66783, Dec. 26, 1991; 56 FR 66783, Dec. 26, 1991]

### § 104.2 Permit authorized.

(a) Animal and Plant Health Inspection Service is authorized to issue three types of permits for importing biological products. They shall be:

(1) U.S. Veterinary Biological Product Permit for Research and Evaluation;

(2) U.S. Veterinary Biological Product Permit for Distribution and Sale; or

(3) U.S. Veterinary Biological Product Permit for Transit Shipment Only.

(b) A permit shall not be issued for a biological product from countries known to have exotic diseases, including but not limited to foot-and-mouth disease, rinderpest, highly pathogenic avian influenza, swine vesicular disease, Newcastle disease, and African swine fever, if in the opinion of the Administrator, such products may endanger the livestock or poultry of this country.

(c) A permit shall not be issued until an inspector has determined the condition of the equipment and facilities of the producer, of the applicant, or of both if such a determination is considered necessary by the Administrator.

(d) A permit shall not be issued for a biological product prepared in the United States, exported, and presented for reentry except as provided in § 104.4(d).

[38 FR 32916, Nov. 29, 1973, as amended at 56 FR 66783, Dec. 26, 1991; 56 FR 66783, Dec. 26, 1991; 78 FR 19085, Mar. 29, 2013]

### § 104.3 Permit application.

(a) Each person desiring to import a biological product shall make written application to Animal and Plant Health Inspection Service for a permit. Application forms are available on the Internet at ([http://www.aphis.usda.gov/animal\\_health/vet\\_biologics/vb\\_forms.shtml](http://www.aphis.usda.gov/animal_health/vet_biologics/vb_forms.shtml)) and application for a permit to import a veterinary biologic for research and evaluation or transit shipment may be made on the Internet at ([http://www.aphis.usda.gov/animal\\_health/permits/vet\\_bio\\_permits.shtml](http://www.aphis.usda.gov/animal_health/permits/vet_bio_permits.shtml)).

(b) The application shall specify the type of permit required, the port of entry at which the product shall be